August 12, 2021

Globus Medical Inc.
% Kelly Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs
2560 General Armistead Ave.
AUDUBON PA 19403

Re: K210912
Trade/Device Name: Excelsius3D™
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, OXO, JAA
Dated: July 20, 2021
Received: July 21, 2021

Dear Dr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

, for

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210912

Device Name
Excelsius3D™

Indications for Use *(Describe)*
Excelsius3D™ is a mobile X-ray system designed for 2D fluoroscopy, 2D digital radiography, and 3D imaging of adult and pediatric patients. The system is indicated for use where a physician benefits from 2D and 3D information on anatomic structures and high contrast objects with high x-ray attenuation such as bony anatomy and metallic objects. Excelsius3D™ images are compatible with image guided systems such as ExcelsiusGPS®.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary: Excelsius3D™

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Contact: Kelly Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs

Date Prepared: July 20, 2021

Device Name: Excelsius3D™

Common Name: Computer-assisted mobile image-intensified fluoroscopic and X-ray system

Classification: Per 21 CFR as follows:
§892.1650 Image-intensified Fluoroscopic X-ray System, Mobile
Product Code(s): OWB, OXO, JAA
Regulatory Class: II

Primary Predicate: Medtronic O-Arm Imaging System (K092564)
Other Predicates: Medtronic O-Arm O2 Imaging System (K200074)
Reference Device: GE Optima XR220amx/XR200amx (K142383)

Purpose:
The purpose of this submission is to request clearance of the Excelsius3D™.

Device Description:
Excelsius3D™ is a mobile X-ray imaging system that combines 2D fluoroscopy, 2D digital radiography, and 3D imaging into one unit for acquisition and visualization of 2D or 3D images of patient anatomy. Excelsius3D™ provides real-time image capture, post-capture processing and visualization, and DICOM storage of images.

Visualization of patient anatomy assists in localizing regions of pathology for preoperative examination, in vivo surgical procedures, and post-surgical analysis. The three imaging modalities can assist physicians with performing complex surgical procedures, such as spinal deformity correction or deep brain stimulation (DBS) placement.

Indications for Use:
Excelsius3D™ is a mobile X-ray system designed for 2D fluoroscopy, 2D digital radiography, and 3D imaging of adult and pediatric patients. The system is indicated for use where a physician benefits from 2D and 3D information on anatomic structures and high contrast objects with high x-ray attenuation such as bony anatomy and metallic objects. Excelsius3D™ images are compatible with image guided systems such as ExcelsiusGPS®.

Technological Characteristics:
The Excelsius3D™ has similar technological characteristics to the predicate devices including the main system components, workflow, user interface, software features, and design. The Excelsius3D™ is comparable to the predicates in terms of intended use, fundamental scientific technology, technological characteristics and principle of operation.

Comparison of Principles of Operation and Technological Characteristics

	Subject Excelsius3D™	**Predicate O-Arm (K092564, K200074)**	**Reference Optima XR220amx (K142383)**
Intended Applications	Orthopaedic, cranial	Orthopaedic, cranial	Orthopaedic, cranial *(& gastrointestinal, thoracic, pulmonary)*
Imaging Modalities	2D fluoroscopy 3D imaging 2D digital radiography	2D fluoroscopy 3D imaging	2D digital radiography
Gantry Motion	Isocentric	Isocentric	N/A
Gantry Rotation	360°	360°	N/A
Gantry Stored Positions	Yes	Yes	N/A
X-ray Tube Type	Rotating anode	Rotating anode	Rotating anode
X-ray Beam/ Collimation Type	Cone beam with x-y shutters	Cone beam with x-y shutters	Cone beam with x-y shutters
Image Acquisition Presets	Yes	Yes	Yes
Method of Image Acquisition	Hand switch or foot pedal	Hand switch or foot pedal	Hand switch
Image Transfer	Yes	Yes	Yes
Cybersecurity	Industry standard protocols	Industry standard protocols	Industry standard protocols

Performance Testing:
Verification and validation testing were conducted on Excelsius3D™ to confirm that the device meets performance requirements under the indications for use and to ensure the system performs as intended.

- Non-clinical system and software verification and validation.
  - Software validation and verification testing was performed in accordance with the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005). The software for this device is considered a "MAJOR" level of concern.
- Electrical Safety and Electromagnetic Compatibility
  - Testing was performed to assure compliance with recognized safety standards for electrical safety and electromagnetic compatibility
    - IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
    - IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: *Electromagnetic disturbances*
    - IEC 60601-1-3:2013 Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: *Radiation protection in diagnostic X-ray equipment*
    - IEC 60601-1-6:2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: *Usability*
    - IEC 60601-2-43:2010 Medical electrical equipment – Part 2-43: Particular requirements for the safety and essential performance of X-ray equipment for interventional procedures
    - IEC 60601-2-54:2015 Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
    - IEC 60825-1:2007 Safety of laser products - Part 1: Equipment classification, and requirements
    - IEC 62304:2015 Medical device software - Software lifecycle processes
    - IEC 62366:2015 Medical devices - Part 1: Application of usability engineering to medical devices
- Image quality assessment comparison and paired image analysis to predicates
- Human cadaveric qualitative validation under clinically relevant scenarios

Basis of Substantial Equivalence:
Excelsius3D™ has been found to be substantially equivalent to the predicate devices with respect to technological characteristics, imaging performance, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate devices.